

## REMARKS

Upon entry of this amendment, claims 1, 20 and 23-33 are pending in the instant application. Claims 23, 26 and 28-30 have been amended herein. Support for the claim amendments presented herein can be found throughout the specification and in the claims as originally filed. For example, support for the chimeric peptides having a length less than 50 amino acids recited by amended claims 23 and 26 is found at least at page 6, lines 6-9. In addition, claims 23, 26, 28 and 29 have been amended to correct a grammatical error. Accordingly, no new matter has been added by these amendments.

### **I. Restriction/Election**

Applicant notes that the Examiner has acknowledged the election without traverse of Group II (*i.e.*, original claims 1-13 and 15-24), drawn to a peptide comprising the generic peptide of SEQ ID NO: 6 including the species of SEQ ID NO:4.

### **II. Priority**

Applicant also notes that the Examiner has acknowledged Applicant's claim for domestic priority under 35 U.S.C. § 119(e) to United States Provisional Application No. 60/158,774, filed October 12, 1999 and under 35 U.S.C. §121 to United States Patent Application No. 09/503,954, filed February 14, 2000. In addition, the Examiner has acknowledged that the amino acid sequences of SEQ ID NO: 4 and SEQ ID NO:8 were disclosed in United States Provisional Application No. 60/158,774.

### **III. Sequence Compliance**

The Examiner has asserted that the application fails to comply with the requirements of 37 C.F.R. 1.821-1.825. According to the Examiner, the specification discloses nucleotide and amino acid sequences (*e.g.*, at page 36, lines 12-13; at page 3, lines 6-8; and in Figures 1 and 2) that have not been identified by sequence identification numbers.

Applicant notes that sequence identification numbers have been added to the nucleic acid and amino acid sequences presented at page 36, lines 12-13 and in amended Figures 1 and 2, as well as those referred to in the descriptions of Figures 1 and 2 at page 3, lines 6-8. In addition,

Applicant submits herewith paper and electronic copies of a Substitute Sequence Listing that includes the nucleic acid sequence presented at page 36, lines 12-13, along with a Statement in Support of the Substitute CRF.

Applicant contends, therefore, that the Substitute Sequence Listing submitted herewith, in conjunction with the amendments presented herein, place this application in compliance with the requirements set forth in 37 C.F.R. §§1.821-1.825. Accordingly, Applicant requests that this objection be withdrawn.

Applicant notes that the Examiner has acknowledged that the sequences presented in SEQ ID NOS: 3, 4, 5, 8, 10 and 14-16 are D retro-inverso peptides and, therefore, are not required in the Substitute Sequence Listing filed herewith.

#### **IV. Specification/Informalities**

The Examiner has indicated that the use of trademark terms, such as, for example, Gene Gun® at page 25, line 13, should be capitalized and accompanied by the generic terminology. Applicant notes that the specification has been amended to capitalize the trademarked term GENE GUN®, and moreover, the use of this trademarked term is preceded in the as-filed specification by the generic terminology, *i.e.*, “microparticle bombardment.” Accordingly, Applicant requests that the Examiner withdraw this rejection.

The Examiner has also objected to the specification for use of the character “□” at page 35, line 20 and at page 36, lines 14-18. Applicant notes that all references to the character “□” in the specification has replaced with the appropriate symbols and/or characters. Accordingly, this objection should also be withdrawn.

Finally, the Examiner has indicated that the specific reference in the first paragraph of the specification does not disclose the relationship between the instant application and the earlier filed application to which this application claims priority (*i.e.*, U.S.S.N. 09/503,954). Applicant notes that the first paragraph of the specification, at page 1, line 4, has been amended to recite that the instant application “is a divisional application of U.S.S.N. 09/503,954, filed February 14, 2000, now issued as United States Patent No. 6,108,820, which claims priority to USSN 60/158,774, filed October 12, 1999”. Accordingly, Applicant requests that the Examiner withdraw this objection as well.

**V. Claim Objections**

The Examiner has objected to claims 23, 26, 28 and 29. In particular, the Examiner has asserted that the term “amino acid sequence” is grammatically incorrect and should be replaced with the term “amino acid sequences.” As suggested by the Examiner, claims 23, 26, 28 and 29 have been amended to replace all references to the term “amino acid sequence” with the term “amino acid sequences.” Accordingly, Applicant requests that the Examiner withdraw this objection.

**VI. Claim rejections under 35 U.S.C. § 112, first paragraph**

***Written Description:***

The Examiner has rejected claims 23, 26, 30 and 31 under 35 U.S.C. § 112, first paragraph for lack of written description. In particular, the Examiner has asserted that these claims recite the term “comprising”, which is “inclusive or open-ended”, as well as the term “peptide”, which does not imply any specific length. According to the Examiner, the peptides of claims 23, 26, 30 and 31 “are not limited to a particular length and can have any number of additional amino acids added to the recited sequences,” and, therefore, one of ordinary skill in the art could not reasonably conclude that Applicant had possession of the invention at the time of filing. (See Office Action, page 5).

Applicants have amended independent claims 23 and 26 similarly. Specifically, the claims have been amended herein to recite a limited group of peptide sequences that are clearly described in the specification.

Claim 23, as amended, has a specific requirement for the peptide sequences that fall within its scope. First, the claimed sequences are limited to a peptide sequence less than 50 amino acids in length that includes the 21 amino acid long sequence of SEQ ID NO:4, the minimum binding domain for JNK inhibition, and the 10 amino acid long sequence of SEQ ID NO:8, the trafficking peptide sequence.

Second, the peptides of claim 23 are further limited to those specific sequences having the recited express characteristic of inhibiting c-jun amino terminal kinase phosphorylation of a specific JNK targeted transcription factor (*i.e.*, c-Jun, ATF2, and Elk1). Support for such peptides is found throughout the specification and in particular, in the Example section,

specifically in Examples 5 and 7 on pages 31-32. This functional limitation eliminates all peptides from the scope of the claim other than those that inhibit JNK phosphorylation.

Claims 26 has been amended similarly, with reference to SEQ ID NOs. 4 and 10.

These claims, as amended, now recite a group of peptides that have defined function. Applicants have provided a clear description of the recited group of peptide sequences that fall within the express and strict requirements of these claims. Applicants have clearly described and defined the methods of determining inhibition of JNK phosphorylation of a JNK transcription factor. For these reasons, Applicant contends that, based on the clear description in the specification, one ordinarily skilled in the art would believe that Applicant was in possession of this limited group of peptides having a defined functional characteristic. This rejection should be withdrawn.

***Enablement:***

The Examiner has also rejected claims 23, 26, 30 and 31 under 35 U.S.C. § 112, first paragraph for lack of enablement. In particular the Examiner has asserted that the claim 23 encompasses “*all chimeric peptides comprising SEQ ID NO:4 and SEQ ID NO:8*” and claim 26 is directed to “*all chimeric peptides comprising SEQ ID NO:4 and SEQ ID NO:10*.” According to the Examiner, “undue experimentation would be required for a skilled artisan to make and/or use the claimed invention.” (See Office Action, pages 6-8).

As noted above, claims 23 and 26 have been amended to require specific structural and functional limitations of the claimed peptide sequences.

Applicants assert that amended independent claims 23 and 26 are enabled by the as-filed specification, and in addition, claims 31 and 33, which depend therefrom, also enabled for the same reasons. Specifically, claim 23 has been amended to require that the chimeric peptides are *less than 50 amino acids long* and includes the sequences defined by SEQ ID NO: 4 and 8. Thus, amended claim 23 and claim 30 which depends therefrom are not directed to “*all peptides*” containing the amino acid sequence of SEQ ID NO:4 and 8, but a clearly defined set of peptides having a unique limitations. Such chimeric peptides are described throughout the specification. (See, e.g., specification at page 6, lines 6-11; at page 7 lines 2-20 and at page 15, lines 5-14) Accordingly, the ordinarily skilled artisan could with routine experimentation, determine which

peptides fall within the claims, and those which did not, by applying the specific and definite criteria expressly recited in the claims.

Claims 26 has been amended similarly. Applicant requests, therefore, that this rejection be withdrawn.

## **VII. Claim Rejections – Double Patenting**

The Examiner has provisionally rejected to claims 1, 20, 25, 26 and 28-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 24, 44, 46, 50, 52, 53 and 58 of copending U.S. Application No. 09/503,954 (“the ‘954 application”). The Examiner also provisionally rejected claims 23 and 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44 and 58 of the ‘954 application. Claims 24, 27, 30 and 32 have also been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44 and 58 of the ‘954 application. Applicant notes that since the mailing of this Office Action, the ‘954 application has issued as U.S. Patent No. 6,108,820 (“the ‘820 patent”).

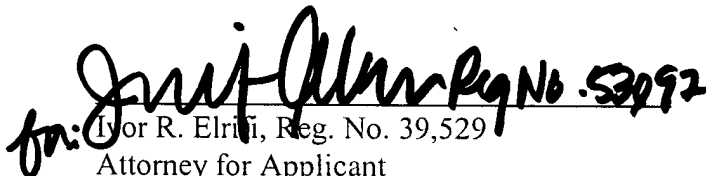
Applicant submits herewith a terminal disclaimer over the ‘820 patent. Accordingly, Applicant requests that the Examiner withdraw these double-patenting rejections.

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U.S.S.N. 09/970,515

### CONCLUSION

On the basis of the foregoing amendments and arguments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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Attachments:

- Appendix A (Replacement Sheets for Figures 1 and 2)
- Appendix B (Annotated Sheets for Figures 1 and 2, Showing Changes)

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# Peptides Sequences, Human, Mouse and Rat

A.

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      :: **.:
IB2      : IPSPSVEEPHKHRPTTLRL--TTLGAQDS SEQ ID NO: 8
IB1      : PGTGCGDTYRPKRPTTLNLFPPQVPRSQDT SEQ ID NO: 17
c-Jun    : GAYGYSNPKILKQSMTLNADPVGNLKPH SEQ ID NO: 19
ATF2     : TNEDHLAVHKHKHEMTLKFGPARNDSVIV SEQ ID NO: 20
  
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B.

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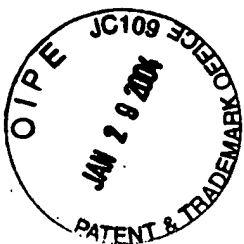
      : . . ***** * **.:
L-IB2    : EEPHKHRPTTLRL--TTLGAQDS SEQ ID NO: 2
L-IB1    : DTYRPKRPTTLNLFPPQVPRSQDT SEQ ID NO: 1
          : ° ° °
  
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C.

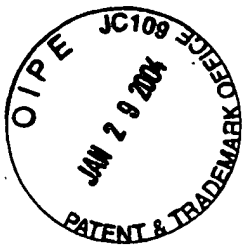
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L-TAT    : NH2- GRKKRRQRRR -COOH SEQ ID NO: 7
L-TAT-IB1 : NH2- GRKKRRQRRRPPDTYRPKRPTTLNLFPPQVPRSQDT -COOH SEQ ID NO: 11
L-TAT-IB2 : NH2- GRKKRRQRRRPPPEEPHKHRPTTLRLTTLGAQDS -COOH SEQ ID NO: 12
D-TAT     : NH2- RRRQRRKKRG -COOH SEQ ID NO: 8
D-TAT-IB1 : NH2- TDQSRPVQPFNLNLTTPRKPRYTDPPRRRQRRKKRG -COOH SEQ ID NO: 14
  
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Fig.1



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## Generic Sequences, Human, Mouse and Rat

L-TAT-IB	: NH <sub>2</sub> -	XXXXXXXXXXRRRRRRXXXXXXXXXXRRPTTLXXXXXXXXXXQDS/TX	-COOH	SEQ ID NO: 13
D-TAT	: NH <sub>2</sub> -	XXXXXXXXXXRRRRRRXXXX -COOH		SEQ ID NO: 8
D-TAT-IB	: NH <sub>2</sub> -	XT/SDQXXXXXXXXXXLTLTTPRXXXXXXXXXXRRRRRRRRKXXXXXXXXXX	-COOH	SEQ ID NO: 16

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Fig.2